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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,042	07/25/2003	Michael Marquant	21084 US/pd-d	4047
23690 7590 05/13/2010 ROCHE DIAGNOSTICS OPERATIONS INC. 9115 Hague Road Indianapolis, IN 46250-0457			EXAMINER HYUN, PAUL SANG HWA	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 05/13/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/628,042	Applicant(s) MARQUANT ET AL.	
	Examiner PAUL S. HYUN	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8 and 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on February 10, 2010 has been acknowledged. Claims 1, 2, 4, 6-8 and 11-22 remain pending. Applicant amended claim 1.

Despite the amendment, the rejections are maintained.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **1, 2, 6, and 15-17 and 19-22** are rejected under 35 U.S.C. 102(b) as being anticipated by Husar (US 2002/0061260 A1).

Husar discloses a device for analyzing liquid samples (see Fig. 2). The device comprises layers (i.e. transport layer 2 and support layer 3) that are sandwiched together to define a plurality of channels and chambers therebetween (see Fig. 14) wherein one channel 5 functions as an inlet and chamber 8 functions as a measuring site. The side of the support layer 3 that faces the transport layer 2 is coated with an electrode layer 17 (see claim 24) comprising a pair of electrodes for electrophoretically separating constituents of the liquid sample wherein one electrode can be made from gold (see [0125]). The device can further comprise optical windows (see [0081]). In one embodiment, Husar discloses a device comprising a plurality of devices stacked together using an adhesive (see [0097]) in a staggered arrangement such that the electrode layer 17 extends beyond an adjacent transport layer 2 (see Fig. 7). Each device can accommodate a unique reagent for measuring a different parameter of the sample liquid (see [0196]).

With respects to claim 19, it should be noted that the claimed control site is limited by the recitation of the intended use of the control site rather than what the control site actually comprises. The limitation “for checking the filling... control site” do not further limit the structure of the control site.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **4 and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Oloman et al. (US 4,118,305).

Husar does not disclose an insulating foil mask in the transport layer.

Oloman et al. disclose a device for conducting reactions wherein the device comprises a pair of electrodes and a porous, hydrophilic insulating material separating the two electrodes (see claim 1). The porous insulating material permits free flow of liquid between the electrodes while providing electrical insulation between the electrodes. In light of the disclosure of Oloman et al., it would have been obvious to one of ordinary skill in the art to provide a hydrophilic, porous insulating layer between the electrodes of the microfluidic device disclosed by Husar so that flow of liquid between the electrodes is permitted while providing electrical insulation between the electrodes.

Claims **7 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Chan (US 5,565,143).

Husar does not disclose the use of an electrode made from Ag/AgCl mixture.

Chan discloses that it is well known in the art to use Ag/AgCl as an electrode in electrophoretic separation applications because the electrode allows the delivery of continuous current at a low and steady voltage (see lines 15-25, col. 1). In light of the disclosure of Chan, it would have been obvious to one of ordinary skill in the art to use Ag/AgCl mixture as one of the electrodes in the device disclosed by Husar.

Claim **14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Stapleton et al. (US 5,922,604).

Although Husar discloses that the device can be pre-packaged with reagents, Husar does not disclose the use of dry reagents.

Stapleton et al. disclose a microfluidic device comprising reagents immobilized to the surface of the microfluidic channels wherein the reagents are dry (see lines 40-50, col. 11). In light of the disclosure of Stapleton et al., it would have been obvious to one of ordinary skill in the art to provide dried reagents to the device disclosed by Husar since dry reagents have longer shelf lives.

Claim **18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Weigl et al. (US 2001/0027745 A1).

Husar does not disclose a vent.

Weigl et al. disclose a microfluidic device comprising vents (see [0100]). The vents facilitate directional flow of fluids inside microfluidic devices by venting trapped air. In light of the disclosure of Weigl et al., it would have been obvious to one of ordinary

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skill in the art to provide vents to the device disclosed by Husar to facilitate that fluid flow.

Response to Arguments

Applicant's arguments with respect to the claims have been fully considered but they are not persuasive.

Applicant argues that the claims as amended are patentable because Husar does not disclose a plurality of transport layers arranged between two support layers. This argument is not persuasive. As indicated in the previous Office action, Husar discloses a device comprising a transport layer 2 having channels formed therein, and a support layer 3 overlying the transport layer 2 to cover the channels formed in the transport layer 2. Husar further discloses an embodiment wherein multiple devices are stacked on top of one another in a staggered arrangement (see Fig. 7). Even though Figure 7 does not show layer 3 overlying each of the transport layers, the reference discloses that each of the "members 2' (i.e. transport layer 2) will be completed by membrane sheetings" (i.e. support layer 3) (see [0168]). Thus in the embodiment illustrated in Figure 7, except for the bottom transport layer, each transport layer 2 is bounded by a pair of support layers 3, one support layer 3 on top of the transport layer, and one support layer 3 supporting the bottom of the transport layer. For the foregoing reason, Applicant's argument that the claims as amended are patentable because Husar does not disclose a plurality of transport layers arranged between two support layers is not persuasive.

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. Applicant argues that the claims as amended are patentable because Husar does not disclose an electrode layer. Applicant supports this position by pointing out that Husar generally teaches functional elements such as membranes and electrodes, not an electrode layer. This argument is not persuasive. It should be noted that the limitation "electrode layer" is subject to the broadest reasonable interpretation. That said, Husar discloses that membrane layer 17 can comprise electrodes (see claim 24 and [0124], note that "planar disposable" referred to in [0124] refers to layer 17). Thus, any layer that comprises electrodes is deemed to be within the scope of the limitation "electrode layer", including layer 17 disclosed by Husar. The Examiner maintains the position that the claims and the Husar reference were properly construed. For the foregoing reason, Applicant's argument that the claims as amended are patentable because Husar does not disclose an electrode layer is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797